

**REMARKS**

This amendment is responsive to the *Final* Office Action of August 22, 2008. Reconsideration and allowance of claims 9-13, 15, 17, 23, 25, and 27-34 are requested.

**The Office Action**

Claims 1, 4, 6, 8-12, 15, 17, 24-30 and 34 stand rejected under 35 U.S.C. § 102 as being anticipated by Nolan (US 5,404,877).

Claims 5, 7, 13, and 15 stand rejected under 35 U.S.C. § 103 as being unpatentable over Nolan in view of Toda (US 2002/0036446).

The Examiner withdrew claims 18, 19, 21-23, and 31-33 from consideration. A Petition challenging the propriety of these claims accompanies this amendment.

**The Present Amendment Should Be Entered**

The present amendment places claim 9 in independent form, including all of the subject matter of its parent claim 1. The present amendment also places claim 27 in independent form including all of the subject matter of its parent claim 1. Further, claim 25 has been placed in independent form, including the subject matter of its parent claim 24. Because a dependent claim is read as including all of the subject matter of its parent claim(s), placing a dependent claim in independent form including the subject matter of its parent claim does not alter the scope of the claim and raises no issues that would require further search or consideration.

Moreover, the present amendment cancels dependent claims 2-8, 24, and 26 which reduces the issues on appeal.

Claims 18, 19, 21, and 22, have been cancelled, without prejudice, to pursue such claims in a timely divisional application, in order to avoid payment of fees for an additional independent claim.

Because this amendment raises no issues that would require further search or consideration, it is submitted that the applicant is entitled to entry of this amendment.

**The Claims Are Not Anticipated By Nolan**

**Claim 9** calls for one or more electrocardiography electrodes. Nolan does not disclose electrocardiography electrodes. Rather than using electrodes, Nolan uses a coil 6 which generates an electromagnetic field which is altered by movement of nearby tissue. An impedance measurement circuit measures a signal from which both pulse rate and respiration rate are derived. Thus, Nolan determines pulse rate without using electrocardiography electrodes.

Second, claim 9 calls for an arrhythmia threshold detector which determines whether the cardiac signals are above or below a "present" threshold. By contrast, Nolan compares heart rate with a threshold that varies with physical activity. Nolan does not include an arrhythmia detector. Rather, Nolan measures heart rate. Moreover, Nolan compares the heart rate with a threshold that changes based on a level of physical activity. It is the variation of the threshold based on physical activity which the Examiner asserts meets the "adaptively controlling" limitation. If one were to change the threshold in Nolan to a preset threshold, then the subject matter which the Examiner has asserted meets the "adaptively controlling" limitation would not be present. (Of course, modifying a reference is inappropriate in an anticipatory rejection).

Third, claim 9 calls for the adaptive controlling to include a means for adaptively controlling the communication of information. Nolan does not adaptively control the communication of the alarm signal to the patient. Rather, Nolan controls the pulse rate threshold adaptively with the level of physical activity. When the alarm condition is reached, Nolan communicates the alarm to the patient without regard to the level of the sensed physical activity. Further, claim 9 calls for the adaptively controlled criteria based on which the alarm signal or other information is communicated to be based on one of the level of the detected activity relative to a threshold, the electrocardiography signals relative to the preset threshold, and/or detected systems errors relative to a predetermined criteria. Nolan communicates its alarm signal via the transmitter/receiver unit 120 and any other information which it might communicate without regard to any of these three criteria.

It is axiomatic that for a reference to be anticipatory, it must disclose every claim limitation. Because Nolan does not disclose the above-three claim

limitations and others, it is submitted that **claim 9 and claims 10-13, 15, 17, and 30 dependent therefrom** are not anticipated by Nolan.

With regard to dependent claims 13 and 15, Toda was not cited as curing any of the above-discussed defects of Nolan and, indeed, does not do so. Accordingly, it is submitted that **claims 13 and 15** distinguish patentably over the references of record.

**Claim 25** calls for a system monitor which not only detects system malfunctions, but also classifies such malfunctions as critical or non-critical. Column 9, lines 10-22 of Nolan referenced by the Examiner do not disclose classifying detected system malfunctions as critical or non-critical. Accordingly, it is submitted that **claim 25** is not anticipated by Nolan.

**Claim 27** calls for a means for determining whether the information about the detected biological signal is urgent or non-urgent. Column 3, lines 28-59 of Nolan referenced by the Examiner do not disclose any means for determining whether a biological signal is urgent or non-urgent. This section of Nolan only determines if the heart rate is normal or abnormal relative to the patient's metabolic demand. This section of Nolan also indicates that the heart motion signal can be analyzed to determine other physiological parameters such as stroke volume or cardiac output. Significant by its absence is any suggestion of determining whether the information about the biological signal is urgent or non-urgent.

**Claim 27** further calls for adaptively controlling the communication of information about the detected biological signal in accordance with the level of sensed physical activity. Column 3, lines 32-44; column 4, lines 16-19; and column 9, lines 23-39 referenced by the Examiner do not disclose controlling communication of information based on physical activity. Rather, these sections of Nolan suggest that the heart rate should be analyzed in light of the patient's physical activity to determine an indication of when the heart rate is inappropriate for the patient's metabolic demand. While the determination of whether the heart rate is appropriate to the metabolic demand is done in accordance with the sensed physical activity, nowhere in Nolan does it suggest that the communication of this information should be controlled in accordance with the level of sensed physical activity. Thus, Nolan determines the information based on the level of physical activity; whereas, claim 27 calls for the

communication of the information to be controlled in accordance with the level of physical activity.

**Claim 28** further refines claim 27 by calling for the communication of information which is non-urgent to be inhibited when the patient is at rest and communicating the non-urgent information when the patient is active. None of the sections referenced by the Examiner disclose communicating non-urgent information when the patient is active and inhibiting the communication of non-urgent information when the patient is at rest.

**Claim 29** calls for inhibiting the communication of information when the detected biological signal is inconsistent with the level of determined physical activity. Nolan teaches directly to the contrary. Specifically, column 3, lines 20-44 disclose that inconsistency between the heart rate and the level of physiological activity *is the alarm condition*. That this inconsistency is the alarm condition is emphasized by column 4, lines 16-50, also referenced by the Examiner. Thus, the referenced sections of Nolan disclose the opposite of this limitation of claim 29. Accordingly, it is submitted that **claims 27, 28, and 29** are not anticipated by Nolan.

Among other limitations, **claim 34** calls for transmitting the alert signal if the patient is active and inhibiting transmission of the alert signal if the patient is at rest. Column 3, lines 28-59 and column 9, lines 1-54 referenced by the Examiner both indicate that the alarm condition is based on whether the heart rate is inconsistent with the patient's metabolic demand. There is no suggestion in these or other sections of Nolan of inhibiting the transmission of the alarm signal of Nolan when the patient is at rest. Accordingly, it is submitted that **claim 34** is not anticipated by Nolan.

Method **claim 23** calls for the step performed by the above-discussed means of claim 34 and is not anticipated by Nolan for the same reasons as claim 34.

#### **Request for Reconsideration of Restriction Requirement**

On May 8, 2008, the Examiner issued a four-way Restriction Requirement between Groups I, II, III, and IV. In the applicant's Amendment of May 29, 2008, the applicant elected Group I, with traverse. The Office Action of August 22, 2008 apparently has withdrawn the Restriction Requirement between Groups I, II,

and IV. The Examiner maintained the Restriction between the elected apparatus claims and the non-elected method claims.

It is submitted that the Examiner has not established a proper basis for Restriction between elected apparatus claim 34 and the non-elected method claims, particularly method claim 23. The Examiner asserts that the method of claim 23 can be performed by a materially different apparatus than the apparatus of claim 34, and that the apparatus of claim 34 can be used in a materially different method than claim 23. The applicant disagrees and hereby petitions this Restriction Requirement.

It will be noted that method claim 23 includes a series of steps and apparatus claim 34 calls for a series of means, specifically a means for performing each of the steps of claim 23.

Claim 23 (withdrawn)	Claim 34 (previously presented)
A method for communicating information about a patient during ambulatory monitoring of a physiological condition of the patient comprising the steps of:	An apparatus for communicating information about a patient during ambulatory monitoring of a physiological condition of the patient comprising:
attaching a physiological monitoring system to a patient;	a physiological monitoring system for attachment to a patient;
detecting a selected physiological parameter of the patient;	means for detecting a selected physiological parameter of the patient with the physiological monitoring system;
sensing physical activity of the patient;	means for sensing physical activity of the patient;
comparing the detected physiological parameter with a first pre-determined criteria to determine a physiological state of the patient reflecting an alarm condition;	means for comparing the detected physiological parameter with a first pre-determined criteria to determine a physiological state of the patient reflecting an alarm condition;
generating an alert signal if the physiological condition of the patient reflects an alarm condition;	means for generating an alert signal if the physiological condition of the patient reflects an alarm condition;
transmitting the alert signal to the patient, if the sensed physical activity of the	means for transmitting the alert signal to the patient if the sensed physical activity

patient indicates the patient is active and inhibiting the transmission of the alert signal if the sensed physical activity of the patient indicates that the patient is at rest.	of the patient indicates the patient is active and inhibiting the transmission of the alert signal if the sensed physical activity of the patient indicates that the patient is at rest.
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As can be seen from the foregoing table, each step of claim 23 has a corresponding means for performing it in claim 34, and vice versa. Accordingly, it is submitted that the apparatus of claim 34 only has means for performing the method of claim 23, and that claim 23 can only be practiced with an apparatus having the means of claim 34.

The Examiner asserts that “the apparatus as claimed can be used by a materially different process, such as a method of stimulating the heart in order to treat trachyarrhythmia versus a method for communicating information about the patient, which is instantly claimed, including the apparatus of claim 34, as argued.” Claim 34 has no means for stimulating the heart. Rather, it has a means for transmitting the alert signal to the patient, i.e., a means for performing the step of transmitting the alert signal to the patient set forth in claim 23. Thus, both the method and the apparatus are for communicating information about the patient and neither includes steps or means for stimulating the heart in order to treat trachyarrhythmia.

Further, the Restriction Requirement was made after a first Office Action on the merits of the claims of all four Groups. Further, the Examiner rejected the independent claims (and most of the dependent claims) of every Group on the same ground of rejection, i.e., as being anticipated by Nolan. (The few dependent method and apparatus claims that were not were all rejected as being obvious over Nolan in view of Toda). Because the method and apparatus claims were both rejected based on the same grounds of rejection over the same reference, it is submitted that they are not directed to a different invention. Moreover, because the Examiner had already performed and issued an Office Action on both the method and apparatus claims, it is submitted that there is no additional burden on the Office to consider both the method and the apparatus claims in this application.

Accordingly, it is submitted that the Restriction Requirement is improper and should be withdrawn. An early withdrawal of the Restriction Requirement is respectfully requested.

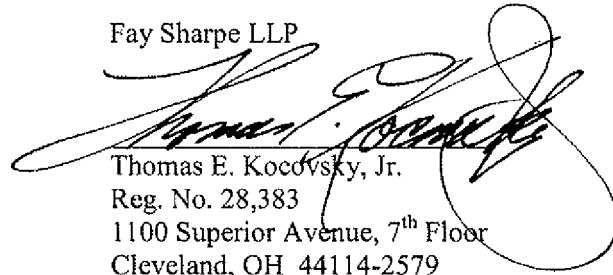
**CONCLUSION**

For the reasons set forth above, it is submitted that the claims are not anticipated by Nolan and distinguish patentably over Nolan and the other references of record. An early allowance of all claims is requested.

In the event the Examiner considers personal contact advantageous to the disposition of this case, she is requested to telephone Thomas Kocovsky at (216) 861-5582.

Respectfully submitted,

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